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Developing a Sound Policy for Encouraging Generic Competition for Biologics

Most Americans believe that the Government should spend enough money on the public health to protect the health of our people, but they also believe that the Government must find ways to control costs so that the health care budget doesn't bankrupt our economy. And most Americans believe that we should encourage the development of new domestic energy sources, but not by adopting policies that will devastate our environment.

A recurring theme in my 30 years in the Congress has been the effort to craft policies that reach the right balance between these types of competing concerns.

In 1984, when the Congress passed the original Hatch-Waxman Amendments, the debate over generic drugs was cast in terms of competing policy concerns. On the one hand, the major drug manufacturers stressed the need for a strong incentive to research and develop new medicines.

On the other hand, consumers and generic manufacturers believed that encouraging competition between brand name drugs and generic drugs would reduce the price of medicine and make it easier for Americans to afford drugs.

My view in 1984 was that our laws then had not yet found the proper balance between these two policy concerns. Our laws were heavily tilted in favor of the brand name manufacturers, so that competition from generic drugs was largely choked off. The drug approval process, as it existed at that time, effectively created permanent monopoly rights for individual drugs. In all but a few cases, the FDA required a would-be competitor to repeat all the original studies on safety and effectiveness to gain approval.

Innovation was well-protected, but the law failed to address the need for access to affordable drugs.

The Hatch-Waxman Amendments sought to address this imbalance. Our goal was to encourage competition from generic drugs, while still giving drug manufacturers adequate incentives to do the research needed to find new drugs. The Act has certainly not been perfect, but it greatly redressed the extreme imbalance between innovation and competition.

In 1984, generic drugs accounted for less than nineteen (19) percent of all prescriptions filled. Today, generic drugs represent more than fifty-one (51) percent of all prescriptions dispensed in the United States. And they have been highly successful in bringing down drug prices, when they are available. It is has been estimated that generic competition can reduce the price of drugs by as much as two-thirds. In the 20 years since passage of the Hatch-Waxman Amendments, I have been pleased and surprised at the law's success in making drugs more affordable for Americans.

But a funny thing happened in those 20 years. A category of drug products that barely existed in 1984, and that we completely ignored in drafting the legislation, slowly emerged as a major source of new medicines. Unfortunately, they also emerged as a major force causing drug prices to rise. I'm talking, of course, about biological drug products.

In 1984, we didn't even think to cover biological drug products, which are regulated under a different statute than traditional drugs. Yet today, more than 150 biotech drugs, which are regulated as biologics, are on the market. In the past year alone, more than 30 new biotech drugs were approved.

These drugs are commanding a larger and larger share of the pharmaceutical market. Analysts estimate that by 2010 biologic sales will exceed $60 billion.

And biotech products pose significant affordability questions. Patients who need these drugs often have to pay tens of thousands of dollars a year for them. And there is evidence that the price of biotech drugs is rising faster than the price of traditional drugs.

There is no currently recognized mechanism for approving generic versions of biological products, and relatively little direct competition in the biologic marketplace. As in 1984, companies who want to gain approval of copies of marketed biologics must repeat all of the safety and effectiveness studies conducted by the innovator. Once again, the FDA approval process is acting as a super-patent, permanently precluding generic competition.

So, in many ways, we are facing much the same dilemma we did in 1984, and the same need to balance competing concerns. On the one hand, the biotech industry needs incentives for innovation. But, on the other, consumers need access to affordable medicines, and competition is needed to bring down drug prices.

As in 1984, I do not believe that current law strikes the right balance. Certainly, some intellectual property protections are appropriate to encourage innovation by brand-name biologics manufacturers. However, under any rational scheme, intellectual property rights must come to an end at some point. Permanent monopolies are neither needed to protect innovation nor even wise. Limits on intellectual property rights promote needed competition.

In fact, I believe that the trade off between encouraging innovation and encouraging competition can be a false one. At some point, creating permanent monopolies can actually discourage innovation. There's less incentive to create a new invention, if you have a permanent monopoly on the old one. So, the current situation, in which manufacturers of biological drugs have, in effect, permanent monopolies is seriously out of balance.

Does this mean that I'm ready to sit down and draft a Son of Hatch-Waxman, creating a streamlined process for approval of generic or "follow-on" biologics? Not quite so fast. Because there's another way in which the situation we face today does not mirror the situation that existed in 1984.

In 1984, it seemed very clear that the FDA knew what studies had to be performed to establish that a generic copy was the "same" as the brand-name drug. The agency had issued regulations several years before laying out the methods for establishing chemical sameness and bioequivalence.

So we in Congress felt comfortable that if a brand-name drug was safe and effective, a generic drug shown to be chemically identical and bioequivalent would be equally safe and effective. From the FDA's standpoint, the methodology for approving generic drugs was clear. We didn't have to worry that each approval decision made by the agency would be the subject of scientific controversy and litigation.

With so much money at stake in each approval decision, this was not an idle worry. Even with relative certainty about the tests necessary to establish generic equivalence to traditional drugs, the Hatch-Waxman Amendments have set some kind of dubious record for the most petitions and lawsuits generated against the FDA.

And even though the science is perfectly clear, the brand-name industry has still managed to sow substantial doubt in the minds of physicians about the safety and effectiveness of generic drugs. That kind of doubt can seriously undermine the value of a generic drug approval system, regardless of how unfair the criticism is.

Today, we have significantly less certainty about how to show that a copy of a biological drug is the "same" as the original drug. You don't need me to tell you that the science behind generic or "follow-on" biologics is contentious. In fact, I'm sure that the

program CBI has put on for you focuses on the scientific controversy swirling around how to establish the equivalence of follow-on biologics.

What does this controversy mean about the prospects for establishing a streamlined approval process for biological drugs? I think it means we have to balance an additional set of competing concerns. On the one hand, we want to make affordable biological drugs available to Americans as quickly as possible. And we don't want to allow exaggerated fears about lack of comparability to delay the availability of those drugs.

On the other side of the equation are actually two concerns. First, we want to be sure that the generic versions of those drugs really are what patients need: that is, safe and effective versions of the brand-name drug.

Second, we don't want the scientific controversy to jeopardize acceptance of generic biologics, or worse, to jeopardize confidence in the generic industry as a whole. If the science behind approving generic biologics is open to reasonable doubt, the brand name industry will make it their mission to destroy the credibility of those generics in the eyes of physicians and patients.

Just look at what they've done to sow mistrust in standard generic drugs without a shred of evidence to back them up. If their attacks upon generic biologics were to be backed by real scientific ammunition, the results could be devastating.

Can we address these competing concerns? My personal view is that we can. I certainly don't have all the answers, but I believe that thoughtful people are already beginning to lay out a path toward balancing the need for rapid access to generic biologics against the need for scientific certainty.

Several facts give me hope. First, and foremost, the FDA appears to be on the verge of setting out the studies it will require for approval of generic versions of certain

biotech drugs that are, by an accident of history, regulated as drugs rather than as biologics. These drugs, insulin and human growth hormone, are among the simplest of biotech drugs.

If the FDA issues guidance on approval of these drugs, it won't provide a blueprint for approval of all biological drugs, by any means. But it will provide the first solid signal that there can be sufficient scientific certainty to approve generic or follow-on versions of some of these drugs.

If the FDA does go forward with guidance on approval of these biologics, it will provide a test of the FDA's ability to create a defensible case-by-case approval process for follow-on biotech drugs.

Because, ultimately, that seems to be where we are headed. If we wait for a one-size-fits-all set of tests for follow-on biologics, like the bioequivalence test for traditional drugs, it could be decades before a patient sees the first follow-on biologic.

And we will have failed utterly to balance the need for scientific certainty against the urgent need for affordable drugs.

The second fact that heartens me is that experience suggests that perhaps we don't have to wait for such a universal test. When I said that we had scientific certainty in 1984 about the tests necessary to establish that a generic and a brand-name drug were the same, I may have exaggerated in one way. I think it's fair to say that we thought we had that certainty, but history proved us wrong.

Within a few years of passage of the Amendments, the FDA was faced with applications for generic drugs for which traditional bioequivalence studies were not useful. Traditional bioequivalence studies focused on the rate and extent of absorption of the drug into the bloodstream. This works fine for orally administered dosage forms. It doesn't work so well for topical drugs or inhaled drugs.

The FDA was forced to establish and defend new methods for establishing the comparable bioavailability of topical and inhaled drugs in order to approve generic applications for these drugs.

This case-by-case approach, while not without controversy, was successful, and the methodology for establishing the bioequivalence of topical and inhaled drugs is now accepted. This suggests to me that we may be able to create a legislative scheme in which the methods of establishing equivalence for each class of biologics are left to be developed by the FDA, as the science evolves. The assistance of outside scientific bodies could be used to add credibility and improve market acceptance of follow-on biologics.

If this sounds easy, it shouldn't. We still have a long way to go before we reach the kind of consensus that will bring about a new approval process for follow-on generics. Nevertheless, I'm more hopeful today than I used to be.

It will take a bipartisan effort to pass meaningful reform in this area. We had a bipartisan effort with the Hatch-Waxman Amendments in 1984, as the name alone tells you. While we're a long way from passing anything today, I think it's possible that we may be able to craft a new bipartisan approach to encouraging generic biologics.

I was heartened to read that Senator Hatch recently remarked at a hearing that if we don't explore "prudent" steps to encouraging generic biologics, drug prices may rise so much that it would endanger Medicare itself. He also made a plea to the brand name biotech industry for a constructive public policy dialogue how to overcome the obstacles to a streamlined approval process for off-patent biologics.

It may not sound like much, that both Democrats and Republicans can agree that we should do something "prudent" about an issue. Nonetheless, I'm hopeful that the fundamental elements may be falling into place for the beginning of a serious bipartisan effort to address follow-on biologics.

I know that there are people in some of the large brand name biotech companies who want to simply block any kind of reform. They argue that if Congress does anything to limit the duration of their monopoly status, it will spell the doom of all research into new biologics. The strategy of opposing any change may have worked for the big drug companies in the past, but it can't succeed much longer. With the rapid spread of biologics and the meteoric rise in the price of biologics, I believe that it simply will not be possible for Congress to stand by and do nothing.

The important thing will be to make sure that the reforms that will inevitably come are thoughtful, careful, and strike the right balance between encouraging innovation and encouraging competition. And I'm hopeful that I'll be able to join together with thoughtful colleagues on the other side of the aisle to find that balance.